REENGINEERING IMPLEMENTATION IN 1999

(What's to be done, when, how do we measure, and who is responsible for doing it?)

PHASE I RE Teams Develop and Test Pilots	PHASE II Offices Implement Approved Pilots	PHASE III Center Incorporates Changes
• GMP – HACCP – OC • BIMO – OC • Rad Health -- OC • Postmarket – OSB	• Recall -- OC • Registration and Listing -- OC • GMP – QSIT -- OC • MDR -- OSB • Hazard Benefit -- * • Information Dissemination - *	• 510(k) -- ODE • IDE/PMA -- ODE • PDP Process -- ODE • 515(b) -- ODE • Standards -- OST • Regulations -- OHIP

* Office location to be determined

Develop and Test Pilots

1. Determine definite milestones/dates for FY 99, and responsible person or office.
2. Give monthly progress report toward milestones to Czars. These updates will also appear in OT News.
3. Identify potential measures of success.
4. Work with Czars during development and report to Center Director periodically.

Implement Approved Pilots

1. Office Director determines person responsible for implementation.
2. Specify milestones (dates) for FY 99.
3. Identify measures of success and how to track. Define specific metrics.
4. Office Directors report progress toward milestones every month to Center Director in RE Directors meetings. These updates will also appear in OT News.
5. Review overall progress with Center Director quarterly and at regular 1-on-1's.

Incorporate Change

1. Office Director identifies measures of success, method of tracking and responsible person.

2. Office Director identifies savings and determine how/when to shift saved resources to RE areas that require additional FTEs or $.

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Reengineering

Phase 1 – Reengineering Teams Develop and Test Pilots

Develop and Test Pilots

1. Determine definite milestones/dates for FY 99, and responsible person or office.
2. Give monthly progress report toward milestones to Czars. These updates will also appear in OT News.
3. Identify potential measures of success.
4. Work with Czars during development, and report to Center Director periodically.

Phase 1 Teams

- GMP – HACCP -- OC
- BIMO -- OC
- Rad Health -- OC
- Postmarket -- OSB

Good Manufacturing Practices – Hazard Analysis and Critical Control Points

Phase 1

Goal: Develop a quality inspection process based on a sound foundation of compliance with current Good Manufacturing Practices (GMP) and incorporate the principles of the Hazard Analysis and Critical Control Points (HACCP) process.

TEAM Initiatives/Pilot	Description	Milestones - Next Steps
GMP Inspection Process 1. Develop Hazard Analysis and Critical Control Points (HACCP) based inspection protocol. 2. Train Industry, FDA employees and inspectors in new techniques.	*Adrianne Galdi – Team Leader* • Establish a HACCP approach for medical devices where manufacturers determine their "critical control points", so that inspections can focus on the critical elements of the manufacturing process. • Develop a manual and other materials for medical device HACCP training course. Work with Association of Food and Drug Officials (AFDO) to make the course and manual available. Graduates of the course will receive "certificates of HACCP course completion" to be issued and recorded by AFDO.	*Overall progress:* • HACCP web page up and running • Six HACCP courses have been taught by the HACCP Team in conjunction with the Seafood Alliance • An IVD manufacturer submitted a second HACCP Plan in January 1999. • The HACCP Team developed its own manual for medical devices and IVDs. This manual will be the new teaching tool for the two HACCP Medical Device Training Courses scheduled for summer 1999 to be conducted by AFDO. *Next Steps:* • HACCP Training will be offered to Center employees at the Tech Center – summer 1999. • The pilot will be previewed for comment on the Web Site – summer 1999. • The inspection pilot is scheduled to begin late summer 1999.

Bioresearch Monitoring Program (BIMO)

Phase 1

Goal: Identify, assess, report and develop strategies for the device bioresearch monitoring process to optimize its functions and ensure that the needs of its customers are fulfilled.

TEAM Initiatives/Pilot	Description	Milestones - Next Steps
BIMO Determine the ideal process for: 1. Patient Protection 2. Validation of Data	*Jean Toth-Allen and Holly Rhodes – Team Leaders* • Protect the rights and welfare of human research subjects • Verify data and information submitted in support of applications to investigate and market new devices.	*Overall progress:* • Held 6 focus group sessions to generate ideas about the ideal BIMO process and solicited comments from internal/external stakeholders (e.g., CDRH and ORA employees; IRBs, industry, consumers). • Conducted phone interviews with clinical investigators and representatives of non-clinical laboratories • Flowcharted the BIMO process relating to IDE/PMA and those 510(k) applications that contain clinical data • Held team go-aways on April 13 and April 20 during which team identified "skinny rabbits" or quick fixes as well as several longer-term projects *Next steps:* • Meet with the RE steering committee and Office Directors to discuss progress to date and possible pilots – June 8, 1999.

Radiological Health

Phase 1

Goal: Enable CDRH to lead a national radiation control program through improved, prioritized processes and strategies to maintain expertise.

Team Initiative/Pilot	Description	Milestones – Next Steps
Radiological Health	*Joanne Barron, team leader*	*Overall progress* • Obtained feedback from stakeholders; held brown bag meetings with staff, held Go-away April 21-22, 1998, to determine stakeholders, desired outputs, and desired outcomes; met with States and FDA staff at CRCPD to elicit comments – May 17-20, 1998 • Determined resource-intensive activities/mandates from Radiation Blueprint/CATRS data August 1998. Charted and analyzed the 24 most important or most costly processes. • Presented Flow charting and initial initiatives/pilots to the RE Steering Committee on April 27, 1999. *Next steps:* • May 1999 – complete the pilot planning for initiatives and identify any additional issues. • June 1999 – develop the pilots to include concept & elements, interface with stakeholder needs, methods, metrics, etc.
1. Information Initiative	• To identify data indicative of product performance and use & population exposures; develop process to distribute/transfer data and knowledge	
2. Priority Initiative	• To develop model for ranking products, identify negative impact on low priority products; develop procedures to update product ranking & incorporate new products.	
3. Policy Response Initiative	• To identify issues that merit policy decisions and who is responsible; identify critical elements in decision criteria, develop procedures & change controls for recording criteria; identify means to make criteria publicly available.	
4. Nonconformance Notifications	• Skinny Rabbit: Prioritize nonconformance issues and involve firms earlier to elicit self-correction of products.	

Postmarket

Phase 1

Goal: Determine what postmarket surveillance should be; create a postmarket system that is useful for CDRH, industry and the public; and define an overall CDRH system that integrates all component postmarket activities.

TEAM Initiatives/Pilot	Description/Goal	Milestones - Next Steps
Postmarket 1. Prioritization of CDRH Efforts 2. Rapid Hazard Identification 3. Interaction of Premarket/Postmarket Information 4. Communications with Community 5. Context for Research Efforts	***Tom Gross and Brian Harvey, team leaders*** • To provide the Center with a user customizable system that collects and consolidates information to optimize the flow and availability of that information. • To provide the Center with a means to rapidly detect, identify and describe new and ongoing medical device hazards • To establish the means for and practice of integrating information from postmarket surveillance into the premarket review process • To enhance information sharing between CDRH and health care professionals, patients, consumers, professional societies and manufacturers. • To enable Center researchers to identify issues where applied scientific research can make significant contributions to understanding the facts underlying questions of safety and effectiveness.	*Overall progress:* • Drafted vision statement of what the process should accomplish (i.e., identify hazards as early as possible in the life of a marketed Product). Started mapping PM processes; and is in the process of developing a website. • Created five sub-teams: Prioritization, Rapid Hazard Identification, Interaction of Premarket/Postmarket Information, Context for Research Efforts; Communication with the Community *Next steps:* • In May, the team will revisit the Society of Organizational Learning Model to generate ideas for pilots. • In early June, the team will hold its first "brown bag" meeting to get focused input from Center employees on the ideal Postmarket Program. • In late June, the team will meet with the RE steering committee and Office Directors to discuss their progress to date. • In July, the team members will participate in a 3 day training on Organizational Learning. • Brief Advisory Panels on Postmarket Evaluation as part of outreach efforts. • Initiate educational efforts to inform CDRH staff of the Postmarket Strategies Committee

Reengineering

Phase 2 – Offices Implement Approved Pilots

Implement Approved Pilots

1. Office Director determines person responsible for implementation.
2. Specify milestones and dates for FY 99.
3. Identify measures of success and how to track. Define specific metrics.
4. Office Directors reports progress toward milestones every month to Center Director in RE Directors meetings. These updates will also appear in OT News.
5. Office Director reviews overall progress with Center Director quarterly and at regular 1-on-1's.

Phase 2 Teams

- Recall -- OC
- Registration and Listing -- OC
- GMP-QSIT -- OC
- MDR -- OSB
- Hazard Benefit -- *
- Information Dissemination -- *

* Office location to be determined

Recall Process

Phase 2

GOAL - Delegate the classification of Class II and III recalls to District Recall Coordinators.. The Center will continue to classify Class I recalls.

Implementation Activities

1. **Prepare District Offices for a new precedent recall process - Chet Reynolds**
   District Recall Coordinators were delegated the authority to classify Class II and III recalls and to submit recall information electronically using an automated Health Hazard Evaluation (HHE) precedent file and a recall reporting interface on CDRH's CenterNet

- All stakeholders evaluated the data elements, software, and WEB interfaces and a final design for the system has been approved.

- All District Offices have been trained to classify recalls by searching the HHE precedent files and to submit recall classification information via the CenterNet's recall reporting interface. .

- All District Offices have used the system to classify Class II or III recalls and 11 out of 21 Districts routinely use the system. These 11 DOs have relatively high device inventories and consequently submit the majority of device recalls..

Next Steps

- Permanently incorporate the HHE precedent and recall reporting system into the Center's new recall database by FY 2000

- Provide device firms access to the HHE precedent system by FY 2000.
  - Access to the HHE precedent system will assist the device industry in determining when to submit corrections and removals (Class I & II recalls) as required by the Reports of Corrections and Removals regulation, 21 CFR Part 806.

2. **Streamline administration of the existing recall process by converting the existing recall data system (Model 204) to an ORACLE relational database by FY 2000.**

Measures of Success

Goal: Have 50-75% of Class II and III recalls classified by District Recall Coordinators
Metric: Compare Class II and III recalls classified by the field in 1999 to the number classified by the field in 1998.
Finding: 1999 (1st Qtr) – Field classified 23% of all recalls via the pilot vs. 13% of all recalls classified via the pilot in 1998. Seventy-one percent (71%) of the recalls classified by the field are Class II.

Goal: Reduce CDRH's recall FTEs. CDRH's recall FTE benchmark is 19.54 FTEs - a three year average.
Metric: Use time reporting to determine any decreases in CDRH's recall FTEs.
Finding: Current CDRH Recall FTEs are estimated to be13.2 for FY '98. This is a reduction of 6.3 FTEs from the 19.54 benchmark.

Registration and Listings

Phase 2

Goal: Design and implement a less burdensome, and more useful registration and listings system.

Implementation Activities

1. Develop improved Registration and Listings process– Bryan Benesch

Accomplishments

- Briefed Center Senior Staff and received approval to amend registration and listing regulations – January 1999
- Published FR announcement about two grassroots industry meetings in California April 20-21, 1999
- Began process to clean up company name database. Will let contract to help support this effort by September 1999.
- Began writing first draft of the proposed amendments, aiming to obtain CDRH clearance by September 1999, propose to publish in the Federal Register January 2000. Lillian Gill is Senior Champion.

2. Establish WWW Registration and Listings Site – Michele Hudson

Identify and overcome technical obstacles to collecting registration and listings information through the Internet

Implementation Activities

Phase I – hired contractor for programming tasks to include developing an MS Access database, and designing a web-based form to retrieve and update registration records.

Accomplishments

- Contractor developed Pilot R&L Web application –September 98.
- Tested Pilot R&L Web Application within CDRH and ORA, March 15-26, 1999. Evaluated comments submitted by test participants, March 29 - April 9, 1999.

Next Steps

- Modify R&L Web Application based on evaluation by participants.

Phase II - begin testing R&L Pilot Web Application with 9 medical device firms **–** late summer 1999.

Measures of Success

Goal: Streamline reporting requirement
Metric: Survey of stakeholders
Finding: The response from stakeholders at the two CA meetings was very positive. Everyone was enthusiastic about WWW registration and listing. There were concerns about the single contact and parent company concepts. These concerns will be addressed in the draft regulatory text.

Goal: Automate process and obtain more reliable information**.**
Metric: Number of firms who are using www
Finding: Upon completion of Phase II, determine frequency of use, ease of use, and test for accuracy of information.

Good Manufacturing Practices – Quality System Inspection Technique

Phase 2

Goal: Develop an inspection process that saves time and increases the focus on key areas of the quality system, while moving closer to global harmonization.

Implementation Activities

Implement the QSIT inspection process based on the 4 major subsystems in the quality systems regulation: 1) Management, 2) Design Control, 3) Production and Process Control, and 4) Corrective and Preventive Action

Accomplishments

- Drafted QSIT Handbook (Inspection Guide) and placed on RE web site 10/9/98
- Conducted QSIT Study/Pilot in Denver, Minneapolis and Los Angeles Districts using trained investigators. Study ran from 10/1/98 through 2/19/99. Completed 42 QSIT inspections.
- Analyzed study findings, conducted validation workshop 3/18/99, wrote final report.

Next Steps

- Revise Compliance Program to incorporate QSIT. Publish Federal Register announcement in spring 1999.
- Complete QSIT CD-ROM based training program for field investigators – late summer/early fall 1999.
- Implement QSIT nationwide – late summer/early fall 1999.

Measures of Success

Goal: Decrease time for comprehensive Quality System Inspections by 20%
Metric: Use data collected on inspection time during QSIT Pilot and compare to historical data.
Finding: Historical data '98 indicates that comprehensive inspections (with design controls) averaged 98 hours vs. data from the Pilot (42 inspections) averaged 57 hours – a 40% decrease. Source QSIT Validation Report 3/18/99.

Goal: Increase focus on key areas of the comprehensive Quality system Inspections
Metric: Use manufacturer and investigator surveys from QSIT Pilot to determine whether inspections were focused. Compare Pilot FDA-483 against historical FDA-483 observations.
Finding: 100% of industry forms and 88% of investigator forms when analyzed indicated that focus was increased. **Note:** focus was previously not measured, but the QSIT Handbook now has "major" focus areas.

Goal: Move quality system inspection closer to global harmonization group's "Guideline for Regulatory Auditing Quality Systems of Medical Device Manufacturers."
Metric: Use data from manufacturers' surveys collected during QSIT Pilot.
Finding: Analysis found that 74% of respondents thought the QSIT inspection was similar to that used by auditing organizations used by the firms. 21% of respondents had no opinion. **Note:** "Notified Bodies" often audit only large firms that are interested in CE marks. Many small firms do not ship to Europe.

Medical Device Reporting (MDR) Process

Phase 2

Goal: Reduce the volume of paper, improve the quality of data, and enhance the effectiveness of adverse-event reporting at a lower cost. The goal also includes expending fewer resources to enter individual reports and more resources to develop streamlined reporting systems that can yield higher-quality information through innovative surveillance methods.

Implementation Activities

1. Surveillance Network - Susan Gardner

A preferred mechanism for User Facility Reporting that will provide a representative sample of adverse-event reports from user facilities.

Accomplishments

- The Device Net (aka Sentinel) pilot ended 9/30/98. Held coordinator debriefing 11/4/98. Final report was submitted January 1999. Briefing for Dr. Henney in February 1999.

Next Steps

- Planning activities for the national Surveillance Network continue and include interviews with experts in the areas of surveillance systems and medical error reporting. Several seminars have been held with experts to discuss key issues.
- Congressional report is due fall of 1999.

2. Summary Reporting - Dave Shindell

An exemption that allows manufacturers of certain devices to submit a quarterly summary of adverse events vs. individual reports. In CY 98, CDRH received 26,500 reports of adverse events via Summary Reporting.

- Evaluate reports and add products as appropriate. Another product selected for potential Summary Reporting could add an additional 3,400 to the total number reported via Summary Reporting
- Continue to work with contractor to develop summary reporting system. The requirement report and system design specifications documents were received in February 1999.
- Continue to apply improved analytical methodology to manufacturer adverse event reports. New analytic methods are included in the Summary Reporting System under development.

3. Retrain Information Analysis Branch Staff – Ann Tornese

A process which will enable personnel hired into technical positions to gain professional skills thereby providing the Center the benefit of more highly skilled personnel without losing valuable employees.

Measures of Success

Goal: Get more useful information via National Surveillance Network.
Metric: Recruit 24 pilot sites.
Finding:

Goal: Increase the number of Summary Reports from 20,000 in CY 98 to 30,000 in CY 99.
Finding: On target. 17,000 summary reports by end of 2nd Qtr 99.

Goal: Evaluate quality of data and analysis for summary reports vs. individual reports.
Metric: Peer review or validation study

Goal: Improve the quality of analytical products.
Metric: Supervisor appraisal
Finding: Several staff now have necessary analytical skills

Hazard Benefit

Phase 2

Goal: Develop more consistent "decision-tree" prioritization systems and interconnect them.

Implementation Activities

Hazard Categorization Questionnaire
A questionnaire based on characteristics and familiarity of a device to determine its hazard level. The three priority initiatives are:

1. A hazard-categorization system to prioritize decision-making, including current reclassification efforts being considered on 510(k) and 515(b)

2. An MDR prioritization system that uses information from premarket and postmarket sources to determine a recommended level of surveillance

3. A prioritization system for assigning routine compliance inspections.

Next Steps

- Sample so many pro-codes and determine sensitivity and specificity of device characterization – Harry Bushar
- Determine a Senior Champion for the process.

Measures of Success

Goal: Identify devices appropriate for reclassification, and reevaluate the Initial class III classifications.
Metric: Use of decision tree by ODE
Finding:

Goal: Assign devices and device groups to the appropriate level of MDR surveillance based on experience to date and level of concern associated with the product.
Metric: Use of decision tree by OSB
Finding:

Goal: Assign individual firms to a frequency Inspection level, based on the Hazard Categorization of their products and the Estimated frequency of their use.
Metric: Use of decision tree by OC
Target: Inspect 50% of Class 3 every 2 years, 13% of Class 2 every 8 years, and no inspections on Class 1.

Information Dissemination

Phase 2

Goal: To get the right information to the right people at the right time and do so in the most cost-efficient manner possible.

Implementation Activities

1. Information Desk – Jim Norman

Establish Information Desk as the primary means of obtaining information from the Center

Completed the second phase of evaluation of CDRH Information Desk Pilot - 1 (report submitted 3/17/99). This information is currently being used to refine the Information Desk Pilot – 2

Next Steps

The CDRH Information Desk Pilot – 2 will likely be built around the following:

- Center-wide scope; the first pilot was limited to OC, OCD, and OSB
- Employ full-time staffers (probably five staffers); the first pilot used part-time staffers
- Use new, detailed Center-wide contact listings, and
- Use networked help desk software, allowing improvements in call tracking, quality control, and development of FAQs/Knowledge Base

Measures of Success

Goal: Improve the quality and timeliness of information provided by CDRH.
Metric: Customer Satisfaction surveys.
Finding: During first pilot, 56.3% of respondents stated their questions/problems were resolved, and 56.3% found the Info Desk very helpful. Also, 65.6% of respondents stated their calls were handled in a timely manner**.**

2. 510(k) Redaction Regulation – Jim Norman

Shift the burden of redacting SD 510(k)s from FDA to sponsors A final draft of the 510(k) redaction regulation was cleared by CDRH and CBER 2/99. FDA's Office of Chief Counsel provided extensive comments 4/99

Next Steps

Revise draft regulation in response to OCC's April 1999 comments.

Goal: Eliminate the need to provide predisclosure notifications and for the CDRH FOI staff to redact any 510(k) submitted <u>after the effective date of the regulation</u>.
Metric: The % of manufacturers who respond within 30 days with the requisite redacted document.

3. **Electronic Communication – Bonnie Markovitz**

Identify new, more efficient methods of communicating with industry, health care professionals, device user facilities, and the public. The subcommittee has prepared a first draft of an *Electronic Communications Handbook,* providing guidance to Center staff concerning effective use of existing electronic communications channels

Next Steps

- Complete the revision of the "Electronic Communications Handbook" and work with OHIP to set-up CDRH focus groups to determine "ease of use."

- Begin Focus Testing -- 3rd quarter of FY99 and Complete Handbook -- 4 quarter of FY99

Goal: Use electronic means of communication to get critical messages to the right place more rapidly while lowering overall costs.
Metric: Not established yet. (some possibilities are paperwork/time reduction)

Reengineering

Phase 3 – Center Incorporates Changes

Incorporate Change

1. Office Director identifies measures of success, method of tracking and responsible person.

2. Office Director identifies savings and determine how/when to shift saved resources to RE areas that require additional FTEs or $.

Phase 3 Teams

- 510(k) -- ODE
- IDE/PMA -- ODE
- PDP Process -- ODE
- 515(b) -- ODE
- Standards -- OST
- Regulations -- OHIP

510(k) Process

Phase 3

Goal: Fully implement the new 510(k) paradigm which should dramatically increase efficiency and reduce the time required to bring new medical devices to market while still ensuring product safety and efficacy.

Implementation Activities

1. **Process Special 510(k)s - Phil Phillips**

   Manufacturer modifies own legally marketed device & determines that a 510(k) is required. When the modification does not affect intended use or fundamental scientific technology, the 510(k) may be submitted with a **"declaration of conformity" to design controls.**

2. **Process Abbreviated 510(k)s – Phil Phillips**

   Manufacturers who want to market a Class I/II that is subject to special controls/ 510(k) controls or recognized standards can submit an abbreviated 510(k) with summary information on special controls/ 510(k) controls and/or **"declaration of conformity" with standards.**

Accomplishments

Met with industry associations to brainstorm methods of increasing manufacturers use of standards. FDA likely will release a list of additional standards it will recognize by April 30, 1999. In cases where either the Abbreviated 510(k) or Special 510(k) processes could have been used, SE letters are being sent to inform manufacturers.

3. **Streamline Traditional 510 (k) Processing - Marjorie Shulman**

   When a manufacturer submits a complete set of data, the goal is to lessen the time that 510(k)s sit in queues awaiting review.

Measures of Success

Goa1: Encourage firms to use this technique so that we can expect to receive 1,000 **Special 510(k)s** in FY 00
Metric: ODE tracking system
Finding: As of the first 6 months in FY 99, CDRH received 173 Special 510(k)s. Received 80 Special 510(k)s in FY 98.
Note: CBER received 4 Special 510(k)s since the inception of the process.

Goal: Encourage firms to use this technique so that we can expect to receive 200 **Abbreviated 510(k)s** in FY 99. Ultimate Goal: Receive 1,000 each FY.
Metric: ODE Tracking System
Finding: As of the first 6 months in FY 99, CDRH received 45 Abbreviated 510(k)s. Received 21 Abbreviated 510(k)s in FY 98.
Note: CBER received 6 Abbreviated 510(k)s since the inception of the process.

Goal: Measure the extent to which **streamlined 510(k)** procedures are being used.
Metric: Staff interviews
Findings: No findings at this time.

Goa1: Traditional 510(k)s (final action) complete 75% of all final actions within 90 days.
Metric: ODE Tracking System
Finding: As of 3/19/99, completed final actions within 90 days for 69% of Traditional 510(k)s received in the first quarter of FY 99. About 75% of applications received in FY 98 had final actions completed within 90 days.

IDE/PMA Process

Phase 3

Goal: Fully implement the new model IDE/PMA development and review process, and to focus resources on high-impact and high-risk products while producing fast and fair review decisions. Further information on the new IDE/PMA model and pilots is available at www.fda.gov/cdrh.

Implementation Activities

Implement New IDE/PMA Review Model - Susan Alpert

Manufacturers will be able to use new processes from IDE through the PMA so that Center can focus resources on high-impact/high-risk products. Issued "New Model Device Development and Review" July 27, 1998 ; document located at http://www.fda.gov/cdrh/pmat/newmod.html.

A. PMA Shell/Modular – Kathy Poneleit and Ashley Boulware

The SOPs for the PMA Shell and Modular Review have been finalized and ODE has been accepting Shells and Modules since April 1998. Documents describing the process can be found at http://www.fda.gov/cdrh/pma/modpmat.html and http://www.fda.gov/cdrh/ode/pmashell.html .

B. Implement Streamlined PMA Review Process - Susan Alpert

Manufacturers of certain products that are well understood and have established review criteria may submit applications for streamlined review. See letter to DCLD industry PMA holders, http://www.fda.gov/cdrh/pmapilot.pdf.

C. Delegation of PMA Sign Off to Division Directors

The redelegation of sign-off authority to Division Directors for some PMA products was published in the F.R. on May 18, 1998. Several PMAs have been down delegated. Staff will respond if any comments are received on the FR notice. (Susan Alpert and Kimber Richter).

Next Steps

- **Product Labeling Pilots** - Two pilots were initiated. One established SOPs for review and closure on final draft labeling, including an interactive meeting with the applicant. The other eliminated re-review of final printed labeling where it is either identical to the draft or contains only minor changes. Staff assessed the results, modified the boilerplate, and made available to all applicants. (Lisa Fisher). http://www.fda.gov/cdrh/pmat/labpmat.html and http://www.fda.gov/cdrh/pmat/pilotpmat.html
- **Summary of Safety & Effectiveness Data (SSED) Templates** - Develop more efficient standardized SSED formats for Standard PMAs and Streamlined PMAs. The final draft is being reviewed with final completion by June 1, 1999, (Bob Gatling).
- **PMA Supplement Document -** Issued FR notice of availability for the draft FDA/HIMA modification document and flowchart for supplements and other changes. Still working on comments. (Kathy Poneleit). Approved protocols will be used to reduce individual supplements; for routine changes, annual reports will be used to capture changes that don't need prior approval. http://www.fda.gov/cdrh/pumasupp.pdf
- **PMA Inspection Project -** Staff will continue development with the Grassroots Premarket Subcommittee. A draft flowchart describing the types of changes to PMA devices that would determine the type of submission and the probability of a PMA inspection has been developed and is in final review stages. Level 1 Guidance Document out to Center Offices for review (Wes Morgenstern).

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Measures of Success

Goal: Complete 65% of PMA reviews first action within 180 days
Metric: ODE tracking system
Finding: As of 3/19/99, completed 50% of PMA and HDE first actions within time frames for applications received in the first quarter of FY 99. Completed 79% of first actions within time frames for applications received in FY 98.

Goal: Extend the streamlined approach to all ODE divisions
Metric: PMA database comment section
Finding: To date, 2 Divisions are using the streamlined approach, and others will be added as appropriate applications are received. Ongoing.

Goal: Complete 50% of Modular Reviews first action within 90 days.
Metric: ODE Tracking System
Finding: Since the inception of the process we have: received and accepted 70 PMA Shells, received 182 PMA Modules - accepted 43, and received 1 PMA Supplement to Module.
Note: Since the inception of the process **CBER** has: received and accepted 1 PMA Shell and received and accepted 1 Module.

Product Development Protocol (PDP) Process

Phase 3

Goal: Fully implement the PDP submission process in the Center, while maintaining safety and effectiveness.

Implementation Activity

Establish the PDP process as an alternative to the submission of a PMA – Kathy Poneleit

This process is based upon early consultation between the sponsor and the FDA that leads to a device development and testing plan acceptable to both parties. This should minimize the risk that the sponsor will pursue a development strategy FDA finds inadequate.

Next Steps

- Continue fine-tuning the PDP process as an alternative to PMA.
- Codify the PDP process through regulations. No target date for this; comments about the process are still being received based on the guidance recently provided to the industry.

Accomplishments

- The FDA received a Notice of Completion (NOC) for the AMS 700 Series Inflatable Penile Prosthesis Product Line that was declared complete on November 2, 1998. This device is indicated for use in the treatment of chronic, organic, male erectile dysfunction (impotence). Additional details can be found at http://www.fda.gov/cdrh/pdf/d970012.pdf
- On July 27, CDRH published a notice of availability of its Draft Guidance For Industry: Contents of a Product Development Protocol in the Federal Register. This guidance was produced by a collaborative effort within CDRH. The guidance was also made available on the CDRH website at http://www.fda.gov/cdrh/pdp/pdpguide.pdf.

Measures of Success

Goal: Complete Review of PDPs.
Metric: ODE Tracking System
Finding: Status for FY 98 and FY99:
14 PDPs Received
8 Summaries Accepted
5 PDPs Approved
5 Reviewed at a Panel Meeting
1 PDP Declared Complete
Note: CBER received and accepted 1 Summary since the inception of the process. They are awaiting 1 PDP.

Goal: Debrief companies and FDA reviewers about their experience.
Metric: Informal contacts (telephone conversations, meetings)
Finding: Ongoing – feedback is mixed, depending on at what stage the process was entered.

Goal: Determine if time and energy are saved by using the PDP process -- ask firms and look at the workload data.
Metric: Informal contacts (telephone conversations, meetings)
Findings: Ongoing – feedback is generally positive.

Goal: Determine if reviewers think PDP is effective.
Metric: Meetings with reviewers.
Finding: Reviewers believe that the process works best if the company and the FDA work interactively, and if the company responds to FDA requests in a timely manner. Reviewers suggested that the company meet with FDA prior to submission to ensure that companies understand the resource commitment and level of detail needed for a successful PDP.

515 (b) Process
Phase 3

Goal: Reduce the preamendment PMA class III device backlog by either reclassification or by issuance of 515(b) final rules; in addition, streamline the PMA process to efficiently review those PMAs submitted in response to the 515(b) final rules.

Implementation Activities

Call for PMAs and Reclassifications – Jim Dillard

Section 515(b) of Medical Device Amendments established a requirement that preamendment class III are subject to premarket approval. SMDA directs that CDRH either reclassify or issue 515(b) final rules for all remaining preamendment class III devices for which the agency has not issued a final rule calling for premarket approval.

- Developed a tracking system for preamendment class III devices.
- Completed 515(i) calls for information for 58 preamendments class III devices and used the Hazard Categorization Questionnaire to assist making decisions regarding either reclassification or issuance of a 515(b) for each device.
- Reclassified 1 preamendment class III device and proposed reclassification of 39 preamendment class III devices.
- Issued 3 disused device 515(b) final rules for 47 preamendment class III devices and a disused device 515(b) proposed rule for 3 devices.
- Developed a team to coordinate and streamline PMA reviews.

Measures of Success

Goal: Establish a tracking system for all preamendment class III devices (disused device 515(b)") and reclassification actions.
Metrics: ODE tracking system.
Finding: The newly established system is currently being modified.

Goal: Complete review of all PMAs submitted in response to 515(b) final rules within 180 days.
Metrics: ODE tracking system.
Finding: All 3 PMAs submitted in response to disused device 515(b) final rules were reviewed within 180 days using the new streamlined review process.

Goal: Issue final rules to reclassify or call for PMAs for all preamendment class III devices by CY 2001.
Metrics: 116 preamendment class III devices were identified in the 1994 Preamendment Class III Devices Strategy.
Findings: 48 preamendments class III devices have final regulations; 42 preamendments class III devices have proposed regulations; 26 are in process.

Standards Process

Phase 3

Goal: Implement the process to provide consensus Standards that will meet Center needs, save resources when used in product review or other processes, and maintain public health protection.

Implementation Activities

1. Expand the Standards database and promote its use throughout FDA - Jim MCCue

Accomplishments

- Database for Standards is now on-line throughout the Center; also purchased other Standards that are available in CDRH library on CD ROM.
- Completed several documents (e.g., Frequently Asked Questions of the Recognition of Standards, and Guidance on the Recognition and Use of Consensus Standards).
- Updated the ODE system to track the use of recognized Standards and the content of declarations of conformity.

Next Steps

- Continue the work of 13 Specialty Task Groups (STGs) to identify further Standards for recognition, to establish Center consensus on Standards issues, and to identify needed Standards development projects.
- Update Standards database, add additional recognized Standards, and make it more flexible to query (e.g. listing Standards by title, words in the Standard, organization name) - ongoing. This new flexibility will be accessible through the CenterNet and facilitate better queries (Eileen Marshall and Terry McDonald).
- Recognize approximately 100 additional standards.

2. Use of Standards in the Review Process - Tim Ulatowski

Accomplishments

- Designed a compliance program to audit a selection of manufacturers who submit declarations of conformity to standards.
- Met with industry associations to brainstorm methods of increasing manufacturers use of standards and overcome barriers to their use. In cases where the Abbreviated 510(k) process could have been used, SE letters are being sent to inform manufacturers and list the benefits.
- Designed CDRH booth and manned it at AAMI meeting to promote use of standards

Next Steps

- Conduct postmarket monitoring of a sample of manufacturers according to established compliance program.
- Conduct training to include an update of the Standards portion of new reviewer training, annual Standards liaison training, and the presentation of Case Studies to specific branches to educate and promote Standards use (ongoing).
- Monitor the impact of using Standards in 510(k) review (Tim Ulatowsky) - ongoing.
- Include standards use issue in upcoming presentations by Center Senior Staff.

Measures of Success

Goal: Recognize 50-100 Standards and make them available to staff.
Metric: Number of standards
Finding: To date, 463 standards have been approved

Goal: Validate quality of 510(k)s
Metric: Audit one in every 10-20 abbreviated submissions and compare review times to those for similar devices that do not declare conformity.
Finding: No audits were performed during FY 98 because there was an insufficient number of 510(k)s submitted that contained declarations of conformity.

Goal: Increased use of Abbreviated 510(k)
Metric: Number of Abbreviated 510(k) submitted
Findings: As of the first 6 months in FY 99, CDRH received 45 Abbreviated 510(k)s, a substantial increase form 21 received in FY 98. We hope to receive about 200 in FY 99, with an ultimate goal of 1,000 each FY.

Regulations Development Process

Phase 3

Goal: Fully implement the streamlined regulations development process to improve the quality and timeliness of regulations.

Implementation Activities

Develop regulations using the new process - Myrna Hanna/Joe Sheehan

The new process is based on having early meetings and consensus prior to writing the regulation and assigning a Senior Champion to expedite the document.

Accomplishments

- Completed Phase I training (overview for Sr. Staff and Champions in June 1997), and Phase II training (Paperwork Reduction Act in May 1998, Reviewing and Editing the Writing of Others September 1998, and Economics Training in November 1998).
- Pilot tested 10 regulations – 6 of the 10 were completed in 20 weeks.
- Developed Phase III (Regulations Writing) training – January 20, 1999.
- Added a segment to training to address Vice-President's initiative on Plain Language for Regulation Writers.

Next Steps

- Train appropriate office staff in Federal Register Document Tracking System (FRDTS) -- 3rd Quarter FY 99
- Customize Chief Legal Officer Software – 4th Quarter FY 99
- Install Documentum Tracking System – 4th Quarter FY 99
- Interview Senior Champions after regulations are completed and get their opinion (pros and cons) as to the benefit of the new process.

Measures of Success

Goal: Use Concept Papers for 100% of major regulations developed.
Metric: Number of Concept Papers used.
Findings: Concept Papers were used on 100% of regulations developed during FY 98 and there was a 50% reduction in number of rewrites.

Goal: Streamline the regulation development process.
Metric: Interviews with Senior Champions after they have used the process.
Findings: Interviews will take place in 4th Quarter FY 99.

Ultimate goal: reduce the processing time required to produce a quality regulation.
Finding: The RE process has helped the regulation staff produce more with a smaller work force. For example, total number of final rules, proposed rules and notices for FY 96 was 87, for FY 97 was 105 and for FY 98 was 114. During this period, staff decreased by 42% (12 to 7).